

### **Remarks**

Claims 1, 2, 10, 12 - 14, 18, 19, 26 - 28, 32 and 33 have been allowed. Claim 3, 6 and 21 have been amended. Claims 4, 5, 7 - 9, 20 and 24 have been cancelled. New claims 36 - 39 have been added. No issue of new matter arises. Support for the amendments and new claims is found in the instant specification as discussed below.

Applicants address the Examiner's remarks in the order presented.

### **Claim Objections**

Claim 21 is objected to as being dependent upon a rejected base claim. The Examiner has noted that Claim 21 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants have amended claim 21 and respectfully request withdrawal of this objection.

### **Rejection under 35 USC §101**

Claim 20 and 24 are rejected under 35 USC §101 as allegedly directed to non-statutory subject matter. Claims 20 and 24 have been cancelled rendering this rejection moot.

### **Rejection under 35 USC §102(e)**

Claims 3-6, 8, 9, 11, 15 - 17, 22 - 25, 29 - 31, 34 and 35 are rejected under 35 USC §102(e) as allegedly being anticipated by Verwaerde et al. Verwaerde et al. teaches sequences that match bases of the instant SEQ ID NO:1 from 156 to 1098, and also has 51 bases in addition inserted within instant SEQ ID NO:1.

Applicants have amended claim 3 to recite "90% or greater sequence identity to the nucleic acid sequence of SEQ ID NO:1" and have amended claims 3 and 6 to recite the functional element of a "forkhead transcription factor binding site". Thus, claims 3 and 6 claim a nucleic acid sequence distinct from Verwaerde et al. Further, new claims 36 - 39 have been added. Support for the new claims and the amendments to claims 3 and 6 can be found throughout the instant specification. For example, support for 90% homology can be found on page 4 beginning at 18. Support for transcription factors may be located on page 4 where the text beginning on line 6 states "This regulatory DNA fragment contains the binding site for the FOXO DAF-16 that is functionally linked to the DAF-2/IR pathway via akt-1. In spite of current knowledge of the daf2/IR signalling pathway, a suitable responsive element to monitor signalling activity for *C. elegans* has not been known in the art." Also, on page 4, a passage beginning on line 31, states "According to the instant invention, a promoter exhibiting the biological activity of the sod-3 promoter means any promoter, which is responsive to forkhead transcription factors, preferably, the FOXO forkhead transcription factors (hereinafter "FOXO's"), particularly, DAF-16." Claims 4 - 5, 8 - 9 and 24 have been canceled. Claims 11, 15 - 17, 22 - 23, 25, 29 - 31 and 34-35 are dependent from claim 3. Claims 3 and 6 do not read upon the disclosure of Verwaerdwer et al. Applicant's respectfully request withdrawal of the rejection under 35 USC §102(e).

### **Rejection under 35 USC §112**

Claims 3 - 9, 11, 15 - 17, 22 - 25, 29 - 31, 34 and 35 are rejected under 35 USC §112 as allegedly failing to comply with the written description requirement. The Examiner contends that neither the instant specification nor the prior art teaches regions of the promoter required for function. The requirements of §112 are met by disclosing to one skilled in the art how to make and use the invention. Nowhere within §112 does it require an application to describe every nuance of an invention. The instant application fully describes SEQ ID NO: 1, discloses that SEQ ID NO:1 contains a binding site for the forkhead transcription factors and provides examples of forkhead transcription factors. Given the instant specification, one skilled in the art has been provided adequate written description to practice the invention by being given the components in which to do so and guidance in how to use the instant invention. By analogy, one is perfectly capable of driving

a car given the car and instruction on how to operate it without needing to understand how each and every component of a combustion engine works. Applicants respectfully request the Examiner withdraw the rejection under §112.

In view of the Amendments to the Claims and associated Remarks, reconsideration and withdrawal of all outstanding rejections is deemed proper. Should the Examiner believe that an interview would facilitate prosecution of this application, Applicants invite the Examiner to contact the undersigned at 908-231-4757.

Applicants respectfully submit that the application is now in condition for allowance and request notice thereof.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'A. M. Szczepaniak', is written over a horizontal line.

Ann Marie Szczepaniak, Reg. No. 52,267  
Patent Agent for Applicant

sanofi-aventis U.S. LLC  
Patent Department  
Route #202-206 / P.O. Box 6800  
Bridgewater, NJ 08807  
Telephone (908) 231-4757  
Telefax (908) 231-2626

Docket No. DEAV2003/0005 US NP